UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, THE STATE OF CALIFORNIA, THE STATE OF DELAWARE, THE DISTRICT OF COLUMBIA, THE STATE OF FLORIDA, THE STATE OF HAWAII, THE STATE OF ILLINOIS, THE STATE OF INDIANA, THE STATE OF LOUISIANA, THE COMMONWEALTH OF MASSACHUSETTS, THE STATE OF MICHIGAN, THE STATE OF NEVADA, THE STATE OF NEW YORK, THE STATE OF TENNESSEE, THE STATE OF TEXAS, THE COMMONWEALTH OF VIRGINIA, and THE STATE OF WISCONSIN e*x rel.* LAUREN KIEFF and WILLIAM LACORTE,	)	
Plaintiffs,	)	
v.	)	Civil Action No. 03-12366-DPW
	)	Civil Action No. 06-11724-DPW
WYETH and PFIZER, INC.,	)	
Defendants.	)	

SECOND AMENDED COMPLAINT OF THE UNITED STATES

The United States brings this action to recover hundreds of millions of dollars that defendant Wyeth failed to pay the Medicaid program by knowingly reporting false and fraudulent prices for its two types of acid suppressant drugs, Protonix tablets ("Protonix Oral") and intravenous Protonix ("Protonix IV").

The Medicaid program provides prescription drug coverage to the nation's poor and disabled and, during the period relevant to this action, was the nation's largest single purchaser of prescription drugs. In response to findings that Medicaid previously was paying the highest prices for prescription drugs, Congress created the Medicaid Drug Rebate Program ("MDRP") to

ensure that the Medicaid program would receive the benefit of the same discounts and prices on drugs that other large public and private purchasers enjoyed. To achieve this objective, Congress required that, in order for a manufacturer's covered outpatient drugs to be eligible for federal payment under Medicaid, the manufacturer must, among other things, report to the Secretary of Health and Human Services ("Secretary") on a quarterly basis the Average Manufacturer Price ("AMP") and "Best Price" for certain drugs. The Secretary then used these figures to calculate a unit rebate amount, which each state used to invoice manufacturers for rebates based on the state's utilization of the drug. Congress intended that, through these rebates, Medicaid would receive the benefit of the lowest price – the Best Price – that the manufacturer had offered.

During the period from 2001 through 2006, Wyeth undermined the fundamental objective of the MDRP by reporting Best Prices for Protonix Oral and Protonix IV that did not reflect the deep discounts on those drugs that Wyeth made available to thousands of hospitals nationwide through a bundled pricing arrangement. Wyeth used the bundled hospital discounts as a marketing tool to drive "spillover" retail sales of Protonix Oral, which Medicaid and other insurers then covered at much higher prices.

Wyeth knew that the reported Best Price for each of its drugs must reflect the effective price resulting from any "bundled" arrangement where discounts were tied to other purchase requirements or conditions. Nevertheless, Wyeth knowingly ignored this requirement and excluded from its Best Price reports the low prices on Protonix Oral and Protonix IV that hospitals realized through Wyeth's bundled discount offers. By reporting false and inflated Best Prices, Wyeth improperly reduced its rebate payments by hundreds of millions of dollars and denied Medicaid the benefit of the low prices it was offering to thousands of hospitals. Accordingly, the United States seeks to recover treble damages, restitution, and civil penalties

pursuant to the False Claims Act and the common law.

Jurisdiction And Venue

1. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1345, 1367(a), and under 31 U.S.C. § 3732. The Court may exercise personal jurisdiction over Wyeth and Pfizer, Inc. ("Pfizer") under 31 U.S.C. § 3732(a), because Wyeth and Pfizer transact business in this District. Venue is proper in this District under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) and (c) because Wyeth and Pfizer transact business in this District.

The Parties

2. Plaintiff United States brings this action on behalf of its agency, the Department of Health and Human Services, which includes the Centers for Medicare & Medicaid Services ("CMS"), formerly the Health Care Financing Administration.

3. Relator Lauren Kieff is a resident of Massachusetts.

4. Relator William LaCorte is a resident of Louisiana.

5. Defendant Wyeth was a Delaware corporation with its headquarters at 5 Giralda Farms, Madison, New Jersey 07940. Wyeth, formerly known as American Home Products, Inc., was the parent of Wyeth Laboratories, Inc., and Wyeth Pharmaceuticals, Inc., formerly known as Wyeth-Ayerst Laboratories, Inc. At all times relevant to the allegations herein, the management, supervision, control, reporting, and financial exchanges by and between Wyeth, Wyeth Pharmaceuticals, Inc., and Wyeth Laboratories, Inc., were so inextricably intertwined that in effect they operated as one single entity. They acted in concert together to foster, facilitate, and promote the unlawful conduct alleged more specifically below. On October 15, 2009, defendant Pfizer acquired Wyeth, and on November 9, 2009, Wyeth converted into a Delaware limited liability company, Wyeth LLC. Wyeth LLC is now a wholly-owned subsidiary of Pfizer.

6. Defendant Pfizer is a Delaware corporation with principal executive offices located at 235 East 42nd Street, New York, New York. On October 15, 2009, Pfizer acquired Wyeth, which became a wholly-owned Pfizer subsidiary.

The False Claims Act

7. The False Claims Act provides, in pertinent part, that any person who:

> (a)(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
>
> (a)(1)(B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; . . . or
>
> (a)(7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government,
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, . . . plus 3 times the amount of damages which the Government sustains because of the act of that person. . . .

31 U.S.C. § 3729.[1] For purposes of the False Claims Act,

> the terms "knowing" and "knowingly" mean that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information,
>
> and no proof of specific intent to defraud is required.

31 U.S.C. § 3729(b) (1986).

[1] The False Claims Act was recently amended pursuant to Public Law 111-21, the Fraud Enforcement and Recovery Act of 2009 ("FERA"), enacted May 20, 2009. Section 3729(a)(1)(B) was formerly Section 3729(a)(2), and is applicable to this case by virtue of Section 4(f) of FERA, while Sections 3279(a)(1) and 3279(a)(7) of the statute prior to FERA, and as amended in 1986, remain applicable here.

8. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 (notes), and 64 Fed. Reg. 47099, 47103 (1999), the False Claims Act civil penalties were adjusted to $5,500 to $11,000 for violations occurring on or after September 29, 1999.

The Medicaid Program

9. Medicaid is a joint federal-state program that provides health care benefits, including prescription drug coverage, for certain groups, primarily to the poor and disabled. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. 42 U.S.C. § 1396a. The federal portion of each state's Medicaid payments, known as the Federal Medical Assistance Percentage, is based on the state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the federal contribution is at least 50 percent, and as high as 83 percent.

The Medicaid Drug Rebate Program

10. In 1990, Congress reviewed the prices that Medicaid was paying for prescription drugs and determined that Medicaid routinely was paying more than other large drug purchasers for prescription drugs, particularly for "single source drugs" (*i.e.*, drugs like Protonix Oral and Protonix IV that were protected by patent). *See* H.R. Rep. No. 101-881, at 96 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2108. Congress further found that, in order to contain skyrocketing drug costs, state Medicaid programs were denying beneficiaries access to needed medications. *See* 136 Cong. Rec. S12954-01, at *S12955 (Sept. 12, 1990). Congress concluded that "Medicaid, the means-tested entitlement program that purchases basic health care for the poor, should have the benefit of the same discounts on single source drugs that other large public and private purchasers enjoy." 1990 U.S.C.C.A.N. at 2108. Congress therefore decided to "establish

a rebate mechanism in order to give Medicaid the benefit of the best price for which a manufacturer sells a prescription drug to any public or private purchaser." *Id.*

11. Under the Medicaid Drug Rebate Statute, each drug manufacturer must enter into a Rebate Agreement with the Secretary in order for its covered outpatient drugs to be eligible for federal payment under Medicaid. 42 U.S.C. § 1396r-8(a)(1). Under the Rebate Statute and Agreement, a manufacturer of a brand name drug, such as Protonix Oral or Protonix IV, has two primary obligations. First, the manufacturer must report on a quarterly basis to the Secretary the drug's AMP and its Best Price. 42 U.S.C. § 1396r-8(b)(3)(A). Second the manufacturer must pay each state a quarterly rebate equal to the total number of drug units (*e.g.*, pills, vials) purchased by the state times the greater of (1) 15.1% of the drug's AMP, or (2) the difference between the AMP and the Best Price. 42 U.S.C. § 1396r-8(c)(1)(A).

12. Based on the manufacturer's reported AMP and Best Price, the Secretary, through CMS, computes the unit rebate amount ("URA"), which the states then use to invoice the manufacturer for the rebate based upon the state's utilization of the drug. Rebate Agreement, I(dd).

13. Any rebate amount paid by a manufacturer to a state reduces the amount spent by the state and accordingly reduces the medical assistance that the federal government provides to the state. 42 U.S.C. § 1396r-8(b)(1)(B).

14. The Rebate Statute defines Best Price as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, [or] nonprofit entity . . . within the United States." 42 U.S.C. § 1396r-8(c)(1)(C)(i). A hospital is a type of "provider," and Best Price must take into account prices offered to hospitals.

15. The Rebate Statute expressly identifies certain narrow categories of prices and transactions that a manufacturer may exclude from Best Price. For example, the Rebate Statute allows manufacturers to exclude prices that "are merely nominal in amount." 42 U.S.C. §§ 1396r-8(c)(1)(C)(ii)(III). Congress intended this exception to "exclude[] those prices that are merely nominal in amount that manufacturers offer to special purchasers, such as the sale of birth control pills for a penny a pack to Planned Parenthood." *See* 136 Cong. Rec. S12954-01, at *S12962 (Sept. 12, 1990). The Rebate Agreement defines the term "nominal" as "any price less than 10% of AMP in the same quarter for which the AMP is computed." Rebate Agreement, I(s). Notwithstanding the exception for prices that are "merely nominal in amount," the Rebate Agreement mandates that Best Price must be adjusted if "cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized." *Id.*, I(d). Moreover, the Rebate Statute provides that a manufacturer's reported Best Price for a drug must reflect "cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates." 42 U.S.C. §§ 1396r-8(c)(1)(C)(ii)(I).

16. The Rebate Agreement expressly requires manufacturers to take into account pricing arrangements involving "bundled sales." A bundled sale refers to "the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately." Rebate Agreement, I(e). In order to report the prices actually realized when there is a bundled sale, the manufacturer must allocate the discount on each drug proportionately to the dollar value of the units of each drug sold under the bundled arrangement. *Id.*, I(d). For example, in a bundled arrangement, if a hospital actually paid a total of only $200 for two drug products that otherwise would have cost

$1000 based upon their respective AMPs, then, under the bundling rules, the effective price for each product would reflect an 80% discount off the AMP for each product. If the 80% discount off AMP resulted in the lowest prices that the manufacturer offered for each of those products in a particular quarter, then those would have been the Best Prices the manufacturer was required to report.

17. The Rebate Agreement provides that, in the absence of guidance, a manufacturer may make reasonable assumptions in calculating its Best Price, but that those assumptions must be consistent with the Rebate Statute and Agreement and must be documented in either a written or electronic record. Rebate Agreement, II(i).

18. The Rebate Agreement further provides that any ambiguities "shall be interpreted in the manner which best effectuates the statutory scheme," and that "nothing in this Agreement shall be construed to require or authorize the commission of any act contrary to law." Rebate Agreement, IX(e), (d).

Wyeth's Use Of Bundled Arrangements With Nominal Prices
To Market Protonix Oral And Protonix IV To Hospitals

19. Protonix Oral and Protonix IV are in a class of drugs called Proton Pump Inhibitors ("PPIs"), which inhibit the production of gastric acid.

20. Wyeth licenses the right to distribute Protonix Oral and Protonix IV in the United States from a German company, Altana Pharma AG.

21. Wyeth submitted separate applications to the Food & Drug Administration ("FDA") for Protonix Oral and Protonix IV, and the FDA subsequently approved the applications separately. Protonix Oral and Protonix IV also have separate National Drug Codes, which are the numbers used, *inter alia*, to report AMPs and Best Prices. See Rebate Agreement, I(o). The National Drug Code for Protonix Oral 40 mg tablets is 00008-0841. The National

Drug Code for Protonix Oral 20 mg tablets is 00008-0843. The National Drug Code for Protonix IV is 00008-0923.

22. Protonix Oral comes in a yellow, oval tablet, and is ingested orally. It is used primarily in the outpatient setting to treat chronic symptoms associated with gastroesophageal reflux disease ("GERD").

23. Protonix IV is a freeze dried powder that is sold in a vial, mixed with a liquid solution, and injected intravenously. It is used almost exclusively in hospitals, primarily in intensive care units. It is not generally used to treat GERD or its symptoms, but rather is used for critical care needs, such as to prevent upper gastrointestinal bleeding or to treat stress ulcer prophylaxis or aspiration pneumonia.

24. Wyeth began selling Protonix Oral in the United States in June 2000. Wyeth began selling Protonix IV in the United States in April 2001. Protonix IV was the only intravenous PPI on the market in the United States until mid-2004.

25. When Wyeth launched Protonix Oral in 2000, the oral PPI market was already saturated with three other oral PPIs (Prilosec, Prevacid and Aciphex), each of which had more FDA-approved indications than Protonix Oral. In an attempt to differentiate itself, Wyeth stressed that it would be the first manufacturer also to offer an intravenous PPI. As the Wyeth Pricing Committee noted as early as June 1999: "Protonix has the advantage of being the first PPI with an I.V. formulation. Otherwise it appears it will be difficult to differentiate Protonix from the other PPI's. Protonix will enter the market as a late entrant in a relatively well satisfied market [and] . . . not have as many [FDA-approved] indications as [its competitors]." (A copy of the minutes from the Wyeth Pricing Committee meeting on June 24, 1999, is attached hereto as Exhibit 1.)

26. Wyeth developed a marketing strategy that capitalized on its dominant position in the intravenous PPI market to drive sales of Protonix Oral in hospitals, and ultimately outside the hospital market in the far more lucrative outpatient retail market. Absent competition in the intravenous PPI market, Wyeth set a high list price for Protonix IV – approximately $20 per vial. The list price for a Protonix Oral tablet was about $3.00. Wyeth then offered steep bundled discounts on Protonix IV and Protonix Oral to those hospitals that agreed to purchase both products under a single contract known as the Protonix Performance Agreement ("PPA").

27. Wyeth knew that purchases of Protonix Oral and Protonix IV under the PPA would result in bundled sales. In order to obtain internal approval of the PPA, Wyeth executives prepared a memorandum describing its purpose. The memorandum, dated March 1, 2000, explicitly stated that the PPA would create a contingent relationship between Protonix Oral and Protonix IV: "[t]he lower I.V. price would be contingent on acceptance and accessibility of the oral tablets." Leaving no doubt that Wyeth executives understood that this contingent relationship created a bundle, the memorandum further explained that the PPA would "offer rebates/discounts up to 80% off of the I.V. product list price *bundled* with up to a 25% rebate/discount off of the oral list price." (Emphasis added.) (The memorandum also provided that, if necessary for competitive reasons, Wyeth would increase the discount on Protonix Oral to a level that rendered the tablet price nominal, as ultimately occurred.) Wyeth's most senior executives, including both the company's Chairman and the Chief Counsel of its pharmaceuticals division, reviewed and approved this memorandum. (A copy of the March 1, 2000, Wyeth memorandum is attached hereto as Exhibit 2.)

28. Not only did Wyeth executives explicitly characterize the contingent relationship between Protonix Oral and Protonix IV within the PPA as "bundled," but in a later case study

touting the success of the Protonix marketing strategy during a Wyeth Executive Leadership Program, a Wyeth consultant described the contracting strategy as follows: "[Wyeth] decided that since they had the only product in injectible form, they would turn this to their advantage, bundling the injectable with sales of the tablets in order to gain faster approvals in the hospital and managed care formularies." (A copy of Chapter 2 of this case study is attached hereto as Exhibit 3.) The Protonix Brand Team at Wyeth later confirmed that "Protonix IV has historically been viewed as a tool to increase the sales of Protonix 40mg tabs." (A copy of the Wyeth request for proposal containing this statement is attached hereto as Exhibit 4.)

29. To implement this bundling strategy, Wyeth's PPA offered tiered discounts on Protonix IV and Protonix Oral if a hospital agreed to make both products "available" within the hospital and if the hospital met certain market share requirements. As Wyeth marketing executives later recounted, they knew that "most hospitals were only recommending one PPI" (Exhibit 3 at 2-4), so that if a hospital made Protonix Oral "available," it would limit the availability of all other PPIs.

30. With respect to the market share requirements, a participating hospital would receive increasing discounts on Protonix Oral and Protonix IV depending upon the level of market share it achieved on purchases of Protonix Oral in the relevant qualifying quarter. Under the PPA, the Protonix Oral market share was defined as the "extended units of Protonix Oral, purchased in any calendar quarter by Hospital either through a wholesaler or on a direct basis from [Wyeth], as reported by IMS International divided by the combined extended units of Prilosec, Prevacid, Aciphex, and Protonix Oral, plus any new Proton Pump Inhibitors or any generic counterparts of these products which exist or may exist during the term of this

Agreement, purchased in said calendar quarter by Hospital either through a wholesaler or direct from the manufacturer of said products, also as reported by IMS International."

31. Wyeth circulated its first version of the PPA beginning in the spring and summer of 2000. (A copy of the first version of the PPA is attached hereto as Exhibit 5.) This PPA, which many hospitals signed in the summer of 2000, provided as follows:

> In consideration of Hospital making Protonix® Oral and IV available within the Hospital, [Wyeth] shall provide Discounts on the purchase of Protonix Oral and IV by Hospital. Discounts from the commencement of this Agreement through 6/30/01 shall be 25% for Protonix Oral and 80% for Protonix IV. Subsequent Discounts are based on Protonix Oral Market Share performance and are applied one full quarter after the end of each measurement quarter; and are in effect for one full quarter. Discounts for the quarter beginning 7/1/01 shall be based on Protonix Oral Market Share performance for the quarter starting 1/1/01. Discounts for subsequent quarters shall be handled in this same manner. The Discount Grid, below, shows the Protonix Oral Market Share requirements for achieving said Discounts.

DISCOUNT GRID

	QUARTERLY PROTONIX ORAL MARKET SHARE	SUBSEQUENT PROTONIX DISCOUNT	
Discount Level	From 1/1/01 to 3/31/01 and Each Quarter Thereafter	ORAL	IV
1	0-19.99%	0%	0%
2	20-39.99%	10%	25%
3	40-59.99%	20%	50%
4	≥60%	25%	80%

The provision in this and later PPA versions that hospitals "mak[e] Protonix® Oral and IV available within the Hospital" effectively required PPA signatories to purchase and to stock both Protonix Oral and Protonix IV.

32. Beginning on or about March 12, 2001, Wyeth began circulating a revised version of the PPA. (A copy of the March 12, 2001, version of the PPA is attached hereto as Exhibit 6.)

33. By April 2001, Wyeth learned that Astra Zeneca was offering some hospitals nominal prices on its new oral PPI, Nexium. Wyeth responded on or about June 1, 2001, by amending the existing PPAs to offer hospital signatories Protonix Oral at a maximum discount of 94%. (A copy of the June 1, 2001, amendment to the PPA is attached hereto as Exhibit 7.)

34. On or about September 3, 2001, Wyeth began circulating another revised version of the PPA. (A copy of the September 3, 2001, version of the PPA is attached hereto as Exhibit 8.)

35. On or about February 21, 2002, Wyeth began circulating another revised version of the PPA. (A copy of the February 21, 2002, version of the PPA is attached hereto as Exhibit 9.)

36. On or about July 1, 2002, Wyeth began circulating another revised version of the PPA. (A copy of the July 1, 2002, version of the PPA is attached hereto as Exhibit 10.)

37. On or about July 1, 2003, Wyeth began circulating another revised version of the PPA. (A copy of the February July 1, 2003, version of the PPA is attached hereto as Exhibit 11.) This version of the PPA not only required that hospitals make Protonix Oral and Protonix IV "available," it also required that hospitals put those products "on Formulary," *i.e.*, on the list of approved drugs within a hospital. This version of the PPA also contained a new discount grid, providing as follows:

	PROTONIX ORAL & IV MARKET SHARE	SUBSEQUENT PROTONIX DISCOUNT	
Discount Level	Beginning 7/1/03 to 0/30/03 And every two-quarter period thereafter	ORAL Beginning 1/1/04	IV Beginning 1/1/04
1	0-19.99%	94%	20%
2	20-39.99%	94%	50%
3	$\geq$ 40%	94%	80%

38. On or about October 1, 2004, Wyeth began circulating another revised version of the PPA. (A copy of the October 1, 2004, version of the PPA is attached hereto as Exhibit 12.)

39. Like Wyeth's senior executives, Wyeth's hospital sales force understood that the PPA created bundled sales of Protonix Oral and Protonix IV. For example, in 2003, one sales representative noted that: "THE DOCS AT [___] FEEL THAT WE ARE TRYING TO SQUEEZE THEM ON THE PRICE OF IV & ORAL...I POINTEDOUT THAT WE BUNDLED THEM TOGETHER." The same year, another Wyeth sales representative noted that he had "Discussed with doc the possibility of getting [Protonix] back on formulary status at the hospital with the bundled package. . . ." In late 2003, a Wyeth sales representative observed that one physician "Loved our marketing Protonix [Oral] bundled with IV," while another Wyeth sales representative observed in 2004 that a physician "was upset with how Wyeth bundled the iv and oral."

40. Not only did Wyeth executives and sales representatives view the PPA as creating a "bundle," hospital pharmacists presented with the PPA shared Wyeth's view. In 2001, Wyeth hired a vendor to conduct a series of interviews with hospital pharmacists who had just signed the PPA. Those interviews, which Wyeth employees audited, included exchanges such as the following:

> Q: You said Oral Protonix costs 28 cents. Is that price and the price of the IV price a bundled relationship?
> A: It is a bundled arrangement. We do have a contract with them that they will be our preferred PPI.
> (Interview of pharmacist at hospital in Missouri)

> Q: Is there any bundle, is there any relationship between the $4.00 a vial and the $.15 a pill?
> A: Yes.
> Q: OK. Can you explain that?
> A: Basically, based on your usage, your market share, if you don't use a certain amount of the Protonix [oral] and IV, then the price of the

IV would jump to $20.
(Interview of pharmacist at hospital in Mississippi)

Q: Let me get this straight. You pay 15 cents for Protonix and $2.35 a pill for Prevacid? I guess the next logical question is why not just go with Protonix?
A: Well we are, that's an excellent question, we are going to go in that direction at the next P&T Committee meeting, and that is on the agenda. We are just waiting to see about the acceptance of the IV form to see if there was enough interest in that because the 15 cents is tied in with putting the IV on formulary.
Q: So, in order to get the 15 cent Protonix price, you got to put the IV on?
A: Exactly, you sure do.
(Interview of pharmacist at hospital in Oklahoma)

Q: But, Paul, even if TAP was more aggressive earlier, and you wanted to use IV Protonix, it seems to me that the Protonix deal is linked. In other words, I assume in order to get that price for IV Protonix, you've got to use their [oral] Protonix.
A: That is correct.
(Interview of pharmacist at hospital in Massachusetts)

Q: What do you think about the bundled deal that Wyeth offered - $.15 for oral and $4 for the IV formulation?
A: I thought it was excellent. Somebody over there should get a raise for doing that.
Q: So you have good feelings about the package?
A: I think it was very beneficial for them. For us, it was a logical choice. Coming up with an IV agent is the smartest thing they could have done. Otherwise, I would just pick another one.
Q: People said the reason they use the oral is because of the IV? What is the benefit to the company?
A: People go home with a prescription for oral.
(Interview of pharmacist at hospital in Florida)

41. Because of its bundling strategy, Wyeth had great success in getting hospitals to agree to the PPA. Close to 90 percent of the hospitals in the United States signed the PPA. Moreover, as a result of the automatic drug substitution practices that Wyeth had anticipated, the majority of participating hospitals achieved the highest market share tiers for Protonix Oral and Protonix IV under the PPA.

42. At these thousands of hospitals, as Wyeth intended and its consultant later recounted, Protonix "gained the loyalty of many doctors who then continued their use of Protonix in their practices outside the hospital." (Exhibit 3 at 2-4.) Moreover, patients who were put on Protonix Oral or Protonix IV in the hospital often continued to use Protonix Oral after they were discharged. As another Wyeth consultant later determined, these two types of "spillover" prescriptions of Protonix Oral yielded hundreds of millions of dollars in retail sales for Wyeth. Medicaid covered many of these sales, which were not subject to the PPA discounts.

43. While Wyeth was extraordinarily successful in getting hospitals to sign the PPA, there were some hospitals that did not agree to sign the PPA. Those hospitals did not receive the same discounts on Protonix Oral and Protonix IV that participating hospitals enjoyed, but instead paid prices at or near list price.

Wyeth's Knowledge That Bundled And Contingent Nominal Prices Could Not Be Excluded From Its Best Price Reports

44. Wyeth knew about the legal provisions pertaining to "bundled sales" or other arrangements affecting price because those provisions are set forth in the Rebate Agreement, which Wyeth signed in order to have its drug products reimbursable by Medicaid. Wyeth also knew about the provisions pertaining to "bundled sales" or other arrangements affecting price because it possessed and reviewed CMS' Medicaid Drug Rebate Operational Training Guide, which set forth examples of bundled sales or other arrangements affecting price.

45. Furthermore, Wyeth knew about the provisions pertaining to "bundled sales" or other arrangements affecting price because it had studied those provisions closely, with the assistance of outside counsel, and had developed policies to implement those provisions. In 1999, Wyeth retained a large national law firm and an independent consultant to conduct an audit

of the company's compliance with the requirements of government drug programs, including the MDRP. The audit was complete by early 2000.

46. As a result of the audit, Wyeth undertook a number of steps to improve its compliance with government program requirements. These steps included: (1) creating a Government Programs Policy Manual ("Policy Manual") that expressed Wyeth's policies on how to comply with the requirements of the MDRP; and (2) creating a new position, Director of Government Contract Compliance.

47. The first edition of Wyeth's Policy Manual was complete by March 2001, and Wyeth later published it on the company's Intranet. The Policy Manual set forth Wyeth's ostensible policy on both nominal prices and bundling. (A copy of Wyeth's Policy Manual is attached hereto as Exhibit 13.)

48. Regarding nominal prices, the Policy Manual specified that "nominally-priced sales" excludable from Best Price consideration were "*non-contingent* prices below 10% of AMP." (Emphasis added.) Subsequent editions of the Policy Manual reiterated this instruction, so that, consistent with the Rebate Statute, it was Wyeth's professed policy to exclude from its Best Price reports only those nominal prices that were offered without accompanying conditions or contingencies, *i.e.*, "merely nominal" prices.

49. Wyeth's Policy Manual also contained a discussion on bundling, which began as follows: "Wyeth recognizes that bundled sales and free goods may also impact the calculation of BP especially when there are contingent relationships among the products in the bundle or proposal." For additional guidance, the Policy Manual referred to CMS' Medicaid Rebate Operational Training Guide. The Guide explained: "The key to identifying a bundled sale is that the sale is *contingent* upon an additional purchase requirement(s)." Medicaid Drug Rebate

Operational Training Guide at F11a (2001) (emphasis in original). (A copy of pages F11-F11c of the Medicaid Drug Rebate Operational Training Guide is attached hereto as Exhibit 14.)

50. By August 2001, Wyeth also had appointed a Director of Government Contract Compliance. The new Director attended a number of conferences on MDRP issues. At many of those conferences, the speakers provided specific guidance, and warnings, about nominal prices and bundling.

51. At a September 2001 conference attended by Wyeth's Director of Government Contract Compliance, a speaker presented a slide on the government's "Current Enforcement Focus" and then posed the question: "Are bundled agreements or nominal priced goods designed to defeat BP?" In a subsequent slide, the speaker cautioned that "Government views [nominal price] as mask for 'free goods' transaction, to avoid including discount in Best Price calculation," and then explained that bundled sales exist "where nominally priced goods are expressly tied to other purchases or formulary status." (Copies of the slides from the September 2001 presentation are attached hereto as Exhibit 15.)

52. At a May 2002 conference attended by Wyeth's Director of Government Contract Compliance, the same speaker reiterated many of the themes from the September 2001 presentation and further explained that "bundled sales" occur when there are "nominally priced goods in a package deal." (Copies of the slides from the May 2002 presentation are attached hereto as Exhibit 16.)

Wyeth's False Best Price Reports

53. As a participant in the MDRP, Wyeth had a legal obligation to make accurate quarterly reports to CMS of the Best Prices in the prior quarter for each of its drug products, including Protonix Oral and Protonix IV. The Rebate Agreement specifically directed that, in

performing its Best Price reporting obligations, Wyeth consider the impact of all discounts and pricing arrangements, including "bundled sales." Rebate Agreement, I(d).

54. Notwithstanding all of the knowledge and training it gathered pertaining to "bundled sales" or other arrangements affecting price, and even though internally it repeatedly referred to the sales of Protonix Oral and Protonix IV under the PPA as "bundled," Wyeth deliberately ignored and recklessly disregarded the "bundled sale" definition in the Rebate Agreement and its own Policy Manual and submitted Best Price reports for Protonix Oral and Protonix IV without taking into account the impact of the PPA on the effective prices that hospitals actually realized for those drugs.

55. Wyeth did not maintain a record of any assumptions it may have made concerning the effect of the PPA discounts on the Best Prices it reported for Protonix Oral and Protonix IV.

56. In any given quarter, had Wyeth considered the 94% PPA discounts on Protonix Oral to be bundled with the 80% or 83% PPA discounts on Protonix IV, the effective discounts on Protonix Oral at many hospitals would have been about 89%, yielding above-nominal prices that Wyeth should have reported as Best Prices. Because of the bundling of Protonix Oral and Protonix IV, Wyeth also should have applied the same effective discount in reporting its Best Prices for Protonix IV.

57. A table showing the AMPs and Best Prices that Wyeth actually reported for the two strengths of Protonix Oral and for Protonix IV is attached hereto as Exhibit 17. A table showing the URAs that the Secretary calculated using those reported AMPs and Best Prices is attached hereto as Exhibit 18. (Because Exhibits 17 and 18 contain information that Wyeth submitted to the Secretary pursuant to the confidentiality provisions of 42 U.S.C. § 1396r-8(b)(3)(D), the government is filing these exhibits separately under seal.) Wyeth paid rebates to

the states based on these URAs. The rebate amounts that Wyeth paid affected the claims that state Medicaid programs in turn submitted to the federal government for medical assistance. *See* 42 U.S.C. § 1396r-8(b)(1)(B). Exemplars of such claims are attached hereto as Exhibit 19.

58. As Wyeth itself recognized, Wyeth's sales of Protonix Oral were not "non-contingent." As a result, even under the terms of Wyeth's own Policy Manual, sales of Protonix Oral at nominal prices under the PPA did not qualify for exclusion from Wyeth's Best Price determinations for that drug.

59. Although Wyeth knew that the PPA generated "cumulative discounts" that "adjust[ed] the prices actually realized" by hospitals on purchases of Protonix Oral and Protonix IV (*see* Rebate Agreement, I(d)), and that sales of those drugs under the PPA were "bundled," Wyeth disregarded the Rebate Agreement requirement that it proportionately allocate the total discount on those products to determine their Best Prices. It neither performed the required reallocation nor documented any reasons justifying its failure to do so.

60. For example, one Massachusetts hospital that signed the PPA received an effective discount of 85.78% off its Protonix Oral and Protonix IV purchases in the third quarter of 2002. That effective discount reflected the fact that, as a result of the PPA bundle, the hospital paid $8,410 for its Protonix Oral and Protonix IV purchases when it otherwise would have paid $59,130 had it purchased those drugs separately and outside the PPA. Had Wyeth applied that 85.78% effective discount, the resulting effective prices for Protonix Oral and Protonix IV would have been far below its reported Best Prices, but above the nominal price threshold, for those drugs.

61. Had Wyeth heeded the reallocation requirement, it would have found that hundreds, if not thousands, of hospitals had purchased Protonix Oral and Protonix IV at prices

far lower than the Best Prices Wyeth reported to CMS from the second quarter of 2001 (when it launched Protonix IV) through the end of 2006. Instead, having consistently and knowingly flouted the Rebate Statute, the Rebate Agreement, the Medicaid Rebate Operational Training Guide, and its own Policy Manual, Wyeth then knowingly reported false and inflated Best Prices for both Protonix Oral and Protonix IV.

62. By failing to account for the effective prices resulting from the PPA, Wyeth reported false and inflated Best Prices for Protonix Oral and Protonix IV to the Secretary, which (1) caused the Secretary to underreport unit rebate amounts to the states, (2) caused the states to seek less in rebates than they were entitled to from Wyeth, (3) caused Wyeth to pay less in rebates than it actually owed, and (4) caused the federal government to pay more than it should have in federal financial participation funds to the states.

63. As a result of its fraudulent conduct, Wyeth saved itself – and took from the Medicaid program – tens of millions of dollars each quarter over more than half a decade.

COUNT I
(False Claims Act, 31 U.S.C. § 3729(a)(1) (1986))

64. Plaintiff United States repeats and realleges each allegation in each of the preceding paragraphs as if fully set forth herein.

65. From the second quarter of 2001 and continuing through the fourth quarter of 2006, Wyeth provided false quarterly submissions to CMS of its Best Prices with respect to Protonix Oral and Protonix IV. As a result of these submissions, Wyeth knowingly caused the States to present false and inflated claims for Medicaid payments to officials of the United States in violation of 31 U.S.C. § 3729(a)(1).

66. By virtue of the false or fraudulent claims that Wyeth caused to be presented, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

COUNT II
(False Claims Act, 31 U.S.C. § 3729(a)(1)(B) (2009))

67. The allegations of the preceding paragraphs are realleged as if fully set forth herein.

68. From the second quarter of 2001 and continuing through the fourth quarter of 2006, Wyeth knowingly made, used or caused to be made or used, false records or statements material to false or fraudulent claims paid or approved by the Government. Specifically, for each quarter beginning with the second quarter of 2001, and continuing through the fourth quarter of 2006, Wyeth knowingly submitted false quarterly statements to CMS of its Best Prices on Protonix Oral and Protonix IV to reduce improperly its rebate obligations to the States under the MDRP. Wyeth's false quarterly statements of its Best Prices on Protonix Oral and Protonix IV caused the States to submit false and inflated submissions to the Federal Government for reimbursement of Medicaid expenditures in violation of 31 U.S.C. § 3729(a)(1)(B).

69. By virtue of the false or fraudulent claims that Wyeth knowingly caused to be presented, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

COUNT III
(False Claims Act, 31 U.S.C. § 3729(a)(7) (1986))

70. The allegations of the preceding paragraphs are realleged as if fully set forth herein.

71. From the second quarter of 2001 and continuing through the fourth quarter of 2006, Wyeth knowingly made, used, and caused to be made and used, false records or statements to conceal, avoid, or decrease obligations to pay or transmit money or property to the government. Wyeth was aware of its obligation under the Rebate Statute, 42 U.S.C. § 1396r-8, to make and to use truthful records or statements regarding the Best Prices on Protonix Oral and Protonix IV. Wyeth also knew that its Best Price submissions would be used by the United States to calculate the unit rebate amount, which would affect the amount of the rebates that Wyeth was obligated to pay to the States for Protonix Oral and Protonix IV.

72. Wyeth knowingly made, used, or caused to be made or used, false records or statements regarding its Best Prices on Protonix Oral and Protonix IV in order to conceal, avoid, or decrease its obligations to pay or transmit money or property to the State Medicaid programs, which are jointly funded by the United States and the States, thus directly resulting in significant financial loss to the United States and the States.

73. By virtue of the false records or statements Wyeth made, used, or caused to be made or used, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

COUNT IV
(Common Law Fraud)

74. The allegations of the preceding paragraphs are realleged as if fully set forth herein.

75. From the second quarter of 2001 and continuing through the fourth quarter of 2006, Wyeth made and/or caused to be made fraudulent statements to the United States of its Best Prices on Protonix Oral and Protonix IV. Wyeth made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that it had a duty to

disclose, with actual knowledge of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for their truth.

76. Wyeth intended that the United States rely upon these material misrepresentations.

77. The United States did in fact rely upon Wyeth's fraudulent misrepresentations. As a result, between 2001 and 2006, the States received substantially smaller rebate payments from Wyeth than they otherwise would have been entitled to receive and the United States paid substantially larger amounts to the States than would have been paid if Wyeth had submitted true and accurate statements of its Best Prices on Protonix Oral and Protonix I.V.

COUNT V
(Unjust Enrichment)

78. The allegations of the preceding paragraphs are realleged as if fully set forth herein.

79. If Wyeth had not falsely inflated its Best Prices, Wyeth would have been required to pay substantially larger rebates to the States, and the United States consequently would have made smaller payments to the States. By retaining monies that were actually owed to the States under the MDRP, Wyeth retained money that was the property of the Medicaid programs and to which it was not entitled.

80. Wyeth has been unjustly enriched by retaining the use and enjoyment of the monies that should have been paid to the States pursuant to the MDRP absent Wyeth's false and fraudulent misrepresentations regarding the Best Prices for Protonix Oral and Protonix IV.

COUNT VI
(Constructive Trust and Disgorgement)

81. The allegations of the preceding paragraphs are realleged as if fully set forth

herein.

82. By this claim, the United States requests a constructive trust and full accounting of all revenues (and interest thereon) and costs incurred by the Medicaid Program as a result of Wyeth submission of false Best Price reports and failure to comply with its obligations under the Medicaid Drug Rebate Statute and Rebate Agreement. By its actions, Wyeth retained money that should have been paid to the States and, as a result, the United States paid more money to the States than it would have had Wyeth paid the appropriate rebate amounts.

83. This Court has the equitable power to impose a constructive trust and order Wyeth to disgorge the entire amount of improperly-retained rebate amounts that Wyeth should have paid to the States.

84. The United States seeks a constructive trust and disgorgement of all unpaid rebates based upon Wyeth's failure to comply with its obligations under the Medicaid Drug Rebate Statute and Rebate Agreement.

WHEREFORE, plaintiff United States of America respectfully requests this Court to enter judgment for plaintiff and against defendants Wyeth and Pfizer on each count of this Complaint, and to impose damages and penalties as follows:

Count I – an amount equal to three times the loss sustained by the Medicaid Program, plus penalties of $11,000 for each false claim or statement;

Count II – an amount equal to three times the loss sustained by Medicaid, plus penalties of $11,000 for each false claim or statement;

Count III– an amount equal to three times the loss sustained by Medicaid, plus penalties of $11,000 for each false claim or statement;

Count IV – an amount equivalent to the loss sustained by Medicaid, plus prejudgment interest;

Count V – an amount equivalent to the loss sustained by Medicaid, plus prejudgment interest; and

Count VI – an amount equivalent to the loss sustained by the Medicaid, plus prejudgment interest.

Dated: February 11, 2016

Respectfully submitted,

THE UNITED STATES OF AMERICA

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Certificate of Service

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing and paper copies will be sent to those indicated as non-registered participants on February 11, 2016.

/s/ *Gregg Shapiro*
Gregg Shapiro
Assistant U.S Attorney